

# Statin & New onset Diabetes : Where is the Truth ?

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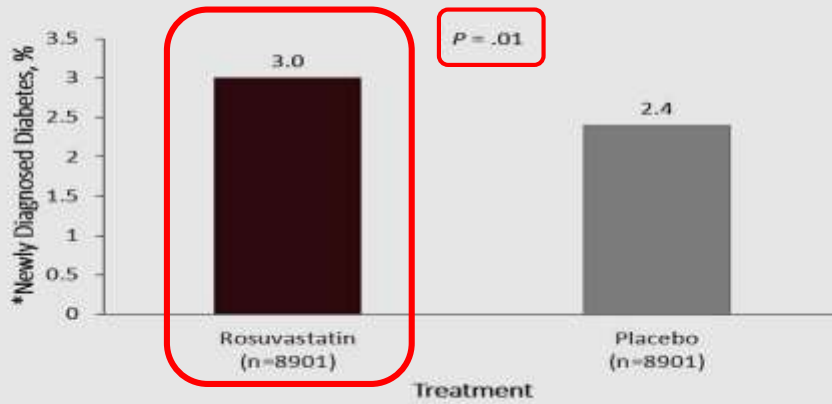
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## THE TRUTH & NOTHING BUT THE TRUTH

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# JUPITER

## Increased Incidence of T2D With Rosuvastatin



\*Physician-reported diabetes.  
 Ridker P, et al. *N Engl J Med.* 2008;359:2195-2207.

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### Certain Statins Increase the Risk of New-Onset T2D

• 13 statin trials

- 9% risk of diabetes over 4 years (n=91,140)

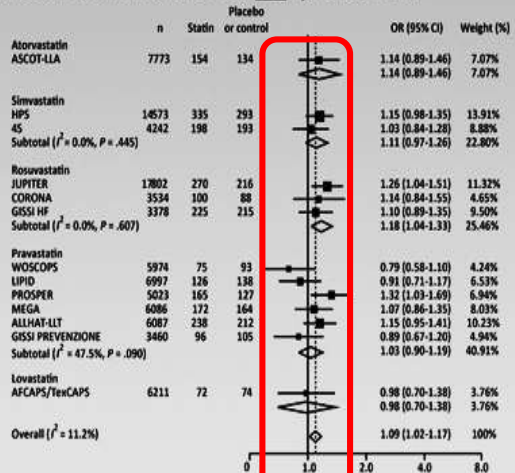
• Results

- Statin therapy is associated with a slightly increased risk of developing diabetes
- Risk is low both in absolute terms and when compared with the reduction in coronary events
- Clinical practice in patients with moderate or high cardiovascular risk or existing cardiovascular disease should not change
- No risk of diabetes if patient is not pre-diabetic

Sattar N, et al. *Lancet* 2010;375:735-742.

### Do Statins Increase New-Onset T2DM?

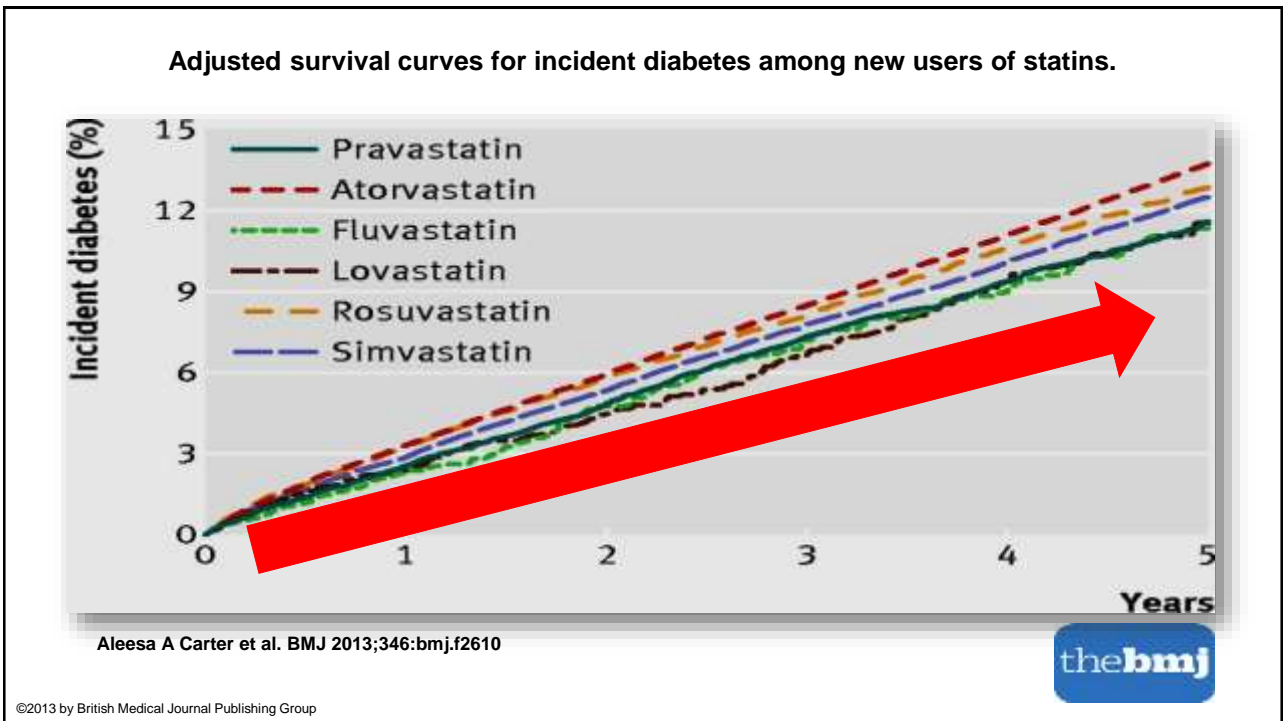
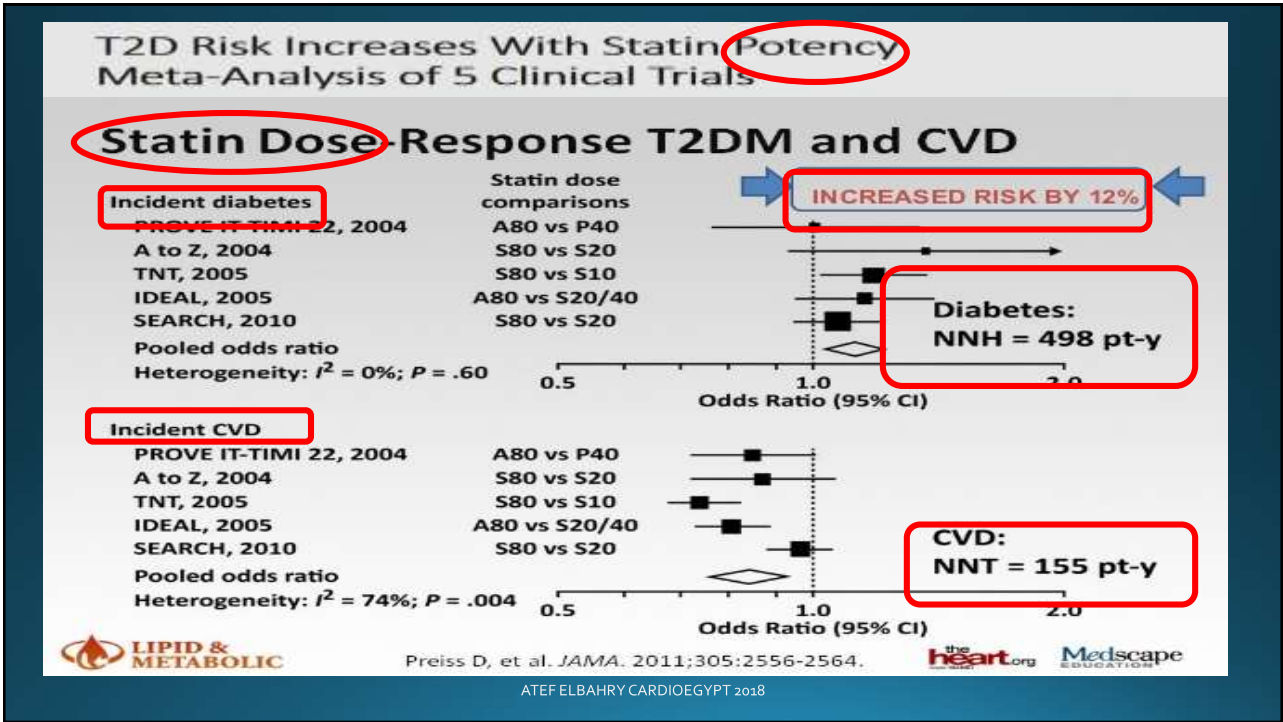
Yes: rosuva, simva, atorva; No: prava, lova



T2DM = type 2 diabetes mellitus  
 Sattar N, et al. *Lancet* 2010;375:735-742.

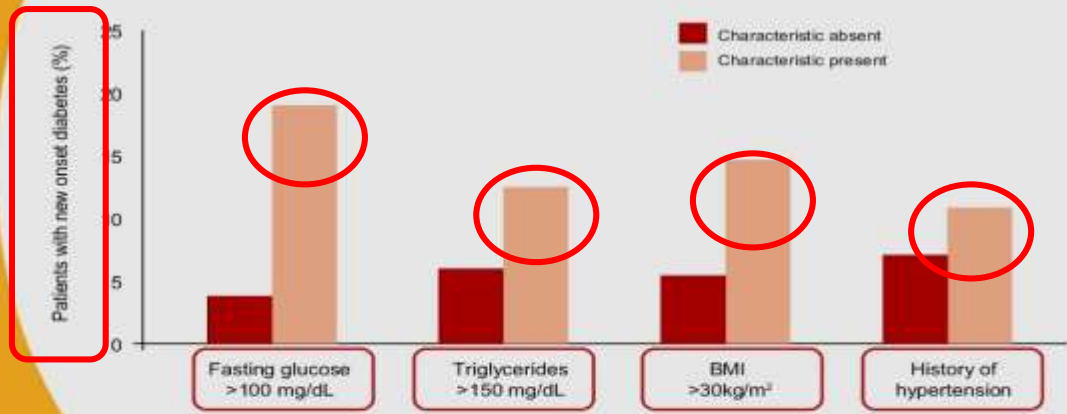


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### Independent Risk Factors for the Development of Diabetes with High Dose Atorvastatin

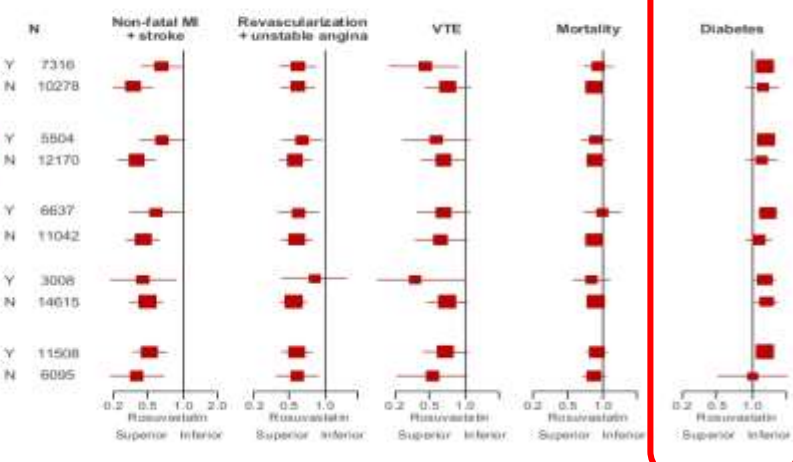
Analysis from TNT\* (n=7,595)



Wazir et al. JACC. 2013;57(14):1538-1545  
TNT: Treat to New Targets

### Risk Factors for the Development of Diabetes in Patients Receiving Rosuvastatin 20mg in the JUPITER\* Trial (n=17,603)

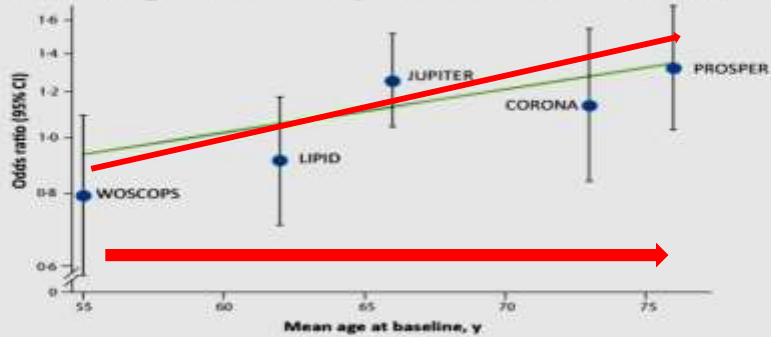
- Metabolic Syndrome
- Fasting glucose  $\geq 5.55$ mmol/L (100mg/dL)
- BMI  $\geq 30$ kg/m<sup>2</sup>
- HbA<sub>1c</sub> >6%
- Any risk factor



Wazir et al. J Am Coll Cardiol. 2012;50(18):1665-1671  
\*JUPITER: Justification for Use of statins in Prevention: an Interventional Trial Evaluating Rosuvastatin

## Risk for New-Onset T2D Stratified by Age

### Meta-Regression Analysis for Incident Diabetes<sup>(a)</sup>



In JUPITER, statin treatment accelerated development of T2D by 5.4 weeks<sup>(b)</sup>

a. Sattar N, et al. *Lancet*. 2010; 375:735-742; b. Ridker P, et al. *Lancet*. 2012;380:565-571.

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83<sup>RD</sup> EAS CONGRESS

March 22 - 25, 2015  
Glasgow, UK

## EFFECT OF HIGH INTENSITY STATINS

### RISK OF INCIDENT DIABETES AMONG PATIENTS TREATED WITH STATINS ± EZETIMIBE: LESSONS FROM A LIPID CLINIC AFTER AN 8-YEAR FOLLOW-UP

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<sup>1</sup>Internal Medicine School of Medicine, University of Ioannina, Ioannina, Greece.

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### Results (II)

- During follow-up for an average of 7 years, 12% of the study participants developed diabetes.
- As expected, individuals with prediabetes at baseline exhibited higher rates of incident diabetes compared with those with normal fasting glucose levels (30% vs 4%,  $p < 0.05$ ).

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### Results (III)

In the multivariate regression analysis:

- \*baseline fasting glucose ( $\beta = 21.68$ ,  $p < 0.01$ ),
- \*presence of the metabolic syndrome ( $\beta = 1.25$ ,  $p < 0.01$ ),
- \*family history of diabetes ( $\beta = 1.08$ ),
- \*duration of follow-up ( $\beta = 1.71$ ,  $p < 0.01$ ),
- \*and high-intensity statin treatment ( $\beta = 1.35$ ,  $p = 0.023$ )

were significantly associated with diabetes development.

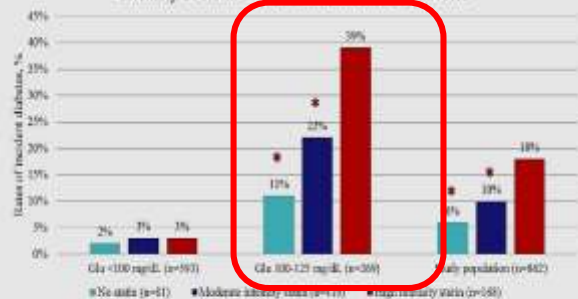


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### Results (IV)

Intensity of statin therapy and incidence of diabetes

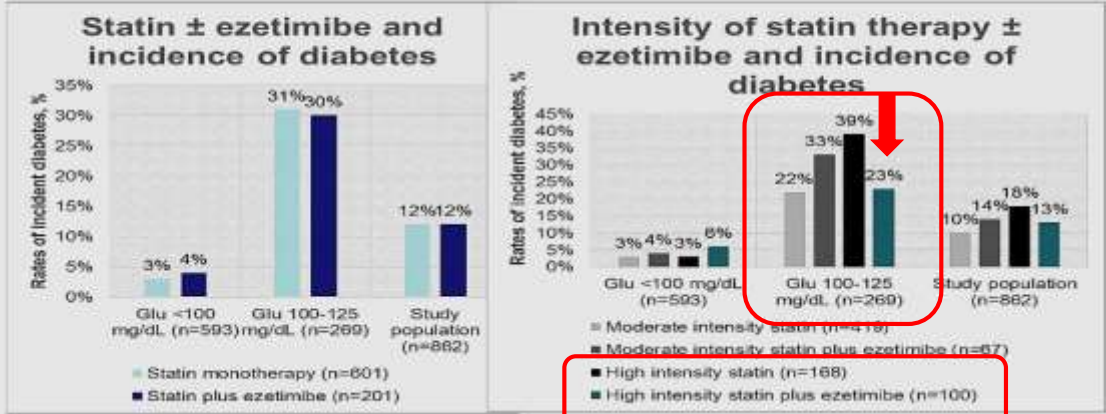


\*  $p < 0.05$  for the comparison with high intensity statin.

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## Results (V)



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## Outcomes

The increased risk is found throughout all subgroups tested, including:

- ✓ Age
- ✓ Race/ethnicity
- ✓ BMI

This holds true even after multivariate adjustment\*

\*Except for African Americans, though this may be due to a lack of power for this subgroup.

**Table 3. Association Between Diabetes Mellitus (DM) Risk and Statin Use Status at Baseline, Within Age, Race/Ethnicity, and BMI Subgroups in 163 640 Participants**

Variable	Patients, No.	Cases of New-Onset DM, No. (%)	Unadjusted HR <sup>†</sup>	Multivariate-Adjusted HR <sup>‡</sup>
<b>Age, y</b>				
50-59				
Statin users	1246	208 (16.6)	1.60 (1.38-1.86)	1.62 (1.39-1.91)
Nonusers	4938	2169 (43.8)	1 (Reference)	1 (Reference)
60-69				
Statin users	1641	568 (34.6)	1.68 (1.52-1.87)	1.67 (1.54-1.82)
Nonusers	6139	4148 (67.6)	1 (Reference)	1 (Reference)
≥70				
Statin users	2017	838 (41.6)	1.65 (1.49-1.84)	1.67 (1.53-1.84)
Nonusers	8018	1862 (23.2)	1 (Reference)	1 (Reference)
<b>Race/Ethnicity</b>				
White				
Statin users	6961	836 (12.0)	1.60 (1.50-1.66)	1.60 (1.50-1.67)
Nonusers	14384	6524 (45.4)	1 (Reference)	1 (Reference)
African American				
Statin users	162	138 (85.2)	1.28 (1.05-1.56)	1.12 (0.90-1.40)
Nonusers	1171	1596 (135.9)	1 (Reference)	1 (Reference)
Hispanic				
Statin users	203	51 (25.1)	1.58 (1.15-2.18)	1.52 (1.14-2.02)
Nonusers	1030	617 (59.7)	1 (Reference)	1 (Reference)
Asian or Pacific Islander				
Statin users	681	98 (14.3)	1.12 (1.04-1.21)	1.12 (1.04-1.21)
Nonusers	2621	264 (10.1)	1 (Reference)	1 (Reference)
<b>BMI</b>				
<25.0				
Statin users	2614	144 (5.5)	1.58 (1.41-1.76)	1.60 (1.43-1.79)
Nonusers	6744	1978 (29.3)	1 (Reference)	1 (Reference)
25.0-29.9				
Statin users	4267	861 (20.2)	1.67 (1.51-1.85)	1.66 (1.50-1.83)
Nonusers	4914	2861 (58.2)	1 (Reference)	1 (Reference)
≥30.0				
Statin users	2549	523 (20.5)	1.23 (1.13-1.35)	1.23 (1.13-1.33)
Nonusers	4513	2838 (62.9)	1 (Reference)	1 (Reference)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HR, hazard ratio; 95% CI, 95% confidence interval.  
<sup>†</sup>By logistic regression model for DM. 95% CI shown.  
<sup>‡</sup>The HRs were adjusted for age, race/ethnicity, education, cigarette smoking, BMI, physical activity, alcohol intake, average triglyceride levels, history of DM, treatment therapy use, study site, and self-report of cardiovascular disease at baseline. Age was not included in models within age subgroups. Gender, race, and BMI were statistically associated in models that adjust for ethnicity and BMI subgroups.

**Table 4. The Status of Baseline in 163 640 Participants**

Age and Race/Ethnicity	Baseline DM	Baseline Adjusted HR <sup>†</sup>	Multivariate-Adjusted HR <sup>‡</sup>
171 (1.0-1.0)	1 (Reference)	1.48 (1.28-1.70)	1.48 (1.28-1.70)
174 (1.1-1.1)	1 (Reference)	1.46 (1.26-1.68)	1.46 (1.26-1.68)
175 (1.2-1.2)	1 (Reference)	1.45 (1.25-1.67)	1.45 (1.25-1.67)
176 (1.3-1.3)	1 (Reference)	1.44 (1.24-1.65)	1.44 (1.24-1.65)
177 (1.4-1.4)	1 (Reference)	1.43 (1.23-1.64)	1.43 (1.23-1.64)
178 (1.5-1.5)	1 (Reference)	1.42 (1.22-1.63)	1.42 (1.22-1.63)
179 (1.6-1.6)	1 (Reference)	1.41 (1.21-1.62)	1.41 (1.21-1.62)
180 (1.7-1.7)	1 (Reference)	1.40 (1.20-1.61)	1.40 (1.20-1.61)
181 (1.8-1.8)	1 (Reference)	1.39 (1.19-1.60)	1.39 (1.19-1.60)
182 (1.9-1.9)	1 (Reference)	1.38 (1.18-1.59)	1.38 (1.18-1.59)
183 (2.0-2.0)	1 (Reference)	1.37 (1.17-1.58)	1.37 (1.17-1.58)
184 (2.1-2.1)	1 (Reference)	1.36 (1.16-1.57)	1.36 (1.16-1.57)
185 (2.2-2.2)	1 (Reference)	1.35 (1.15-1.56)	1.35 (1.15-1.56)
186 (2.3-2.3)	1 (Reference)	1.34 (1.14-1.55)	1.34 (1.14-1.55)
187 (2.4-2.4)	1 (Reference)	1.33 (1.13-1.54)	1.33 (1.13-1.54)
188 (2.5-2.5)	1 (Reference)	1.32 (1.12-1.53)	1.32 (1.12-1.53)
189 (2.6-2.6)	1 (Reference)	1.31 (1.11-1.52)	1.31 (1.11-1.52)
190 (2.7-2.7)	1 (Reference)	1.30 (1.10-1.51)	1.30 (1.10-1.51)
191 (2.8-2.8)	1 (Reference)	1.29 (1.09-1.50)	1.29 (1.09-1.50)
192 (2.9-2.9)	1 (Reference)	1.28 (1.08-1.49)	1.28 (1.08-1.49)
193 (3.0-3.0)	1 (Reference)	1.27 (1.07-1.48)	1.27 (1.07-1.48)
194 (3.1-3.1)	1 (Reference)	1.26 (1.06-1.47)	1.26 (1.06-1.47)
195 (3.2-3.2)	1 (Reference)	1.25 (1.05-1.46)	1.25 (1.05-1.46)
196 (3.3-3.3)	1 (Reference)	1.24 (1.04-1.45)	1.24 (1.04-1.45)
197 (3.4-3.4)	1 (Reference)	1.23 (1.03-1.44)	1.23 (1.03-1.44)
198 (3.5-3.5)	1 (Reference)	1.22 (1.02-1.43)	1.22 (1.02-1.43)
199 (3.6-3.6)	1 (Reference)	1.21 (1.01-1.42)	1.21 (1.01-1.42)
200 (3.7-3.7)	1 (Reference)	1.20 (1.00-1.41)	1.20 (1.00-1.41)
201 (3.8-3.8)	1 (Reference)	1.19 (0.99-1.40)	1.19 (0.99-1.40)
202 (3.9-3.9)	1 (Reference)	1.18 (0.98-1.39)	1.18 (0.98-1.39)
203 (4.0-4.0)	1 (Reference)	1.17 (0.97-1.38)	1.17 (0.97-1.38)
204 (4.1-4.1)	1 (Reference)	1.16 (0.96-1.37)	1.16 (0.96-1.37)
205 (4.2-4.2)	1 (Reference)	1.15 (0.95-1.36)	1.15 (0.95-1.36)
206 (4.3-4.3)	1 (Reference)	1.14 (0.94-1.35)	1.14 (0.94-1.35)
207 (4.4-4.4)	1 (Reference)	1.13 (0.93-1.34)	1.13 (0.93-1.34)
208 (4.5-4.5)	1 (Reference)	1.12 (0.92-1.33)	1.12 (0.92-1.33)
209 (4.6-4.6)	1 (Reference)	1.11 (0.91-1.32)	1.11 (0.91-1.32)
210 (4.7-4.7)	1 (Reference)	1.10 (0.90-1.31)	1.10 (0.90-1.31)
211 (4.8-4.8)	1 (Reference)	1.09 (0.89-1.30)	1.09 (0.89-1.30)
212 (4.9-4.9)	1 (Reference)	1.08 (0.88-1.29)	1.08 (0.88-1.29)
213 (5.0-5.0)	1 (Reference)	1.07 (0.87-1.28)	1.07 (0.87-1.28)
214 (5.1-5.1)	1 (Reference)	1.06 (0.86-1.27)	1.06 (0.86-1.27)
215 (5.2-5.2)	1 (Reference)	1.05 (0.85-1.26)	1.05 (0.85-1.26)
216 (5.3-5.3)	1 (Reference)	1.04 (0.84-1.25)	1.04 (0.84-1.25)
217 (5.4-5.4)	1 (Reference)	1.03 (0.83-1.24)	1.03 (0.83-1.24)
218 (5.5-5.5)	1 (Reference)	1.02 (0.82-1.23)	1.02 (0.82-1.23)
219 (5.6-5.6)	1 (Reference)	1.01 (0.81-1.22)	1.01 (0.81-1.22)
220 (5.7-5.7)	1 (Reference)	1.00 (0.80-1.21)	1.00 (0.80-1.21)
221 (5.8-5.8)	1 (Reference)	0.99 (0.79-1.20)	0.99 (0.79-1.20)
222 (5.9-5.9)	1 (Reference)	0.98 (0.78-1.19)	0.98 (0.78-1.19)
223 (6.0-6.0)	1 (Reference)	0.97 (0.77-1.18)	0.97 (0.77-1.18)
224 (6.1-6.1)	1 (Reference)	0.96 (0.76-1.17)	0.96 (0.76-1.17)
225 (6.2-6.2)	1 (Reference)	0.95 (0.75-1.16)	0.95 (0.75-1.16)
226 (6.3-6.3)	1 (Reference)	0.94 (0.74-1.15)	0.94 (0.74-1.15)
227 (6.4-6.4)	1 (Reference)	0.93 (0.73-1.14)	0.93 (0.73-1.14)
228 (6.5-6.5)	1 (Reference)	0.92 (0.72-1.13)	0.92 (0.72-1.13)
229 (6.6-6.6)	1 (Reference)	0.91 (0.71-1.12)	0.91 (0.71-1.12)
230 (6.7-6.7)	1 (Reference)	0.90 (0.70-1.11)	0.90 (0.70-1.11)
231 (6.8-6.8)	1 (Reference)	0.89 (0.69-1.10)	0.89 (0.69-1.10)
232 (6.9-6.9)	1 (Reference)	0.88 (0.68-1.09)	0.88 (0.68-1.09)
233 (7.0-7.0)	1 (Reference)	0.87 (0.67-1.08)	0.87 (0.67-1.08)
234 (7.1-7.1)	1 (Reference)	0.86 (0.66-1.07)	0.86 (0.66-1.07)
235 (7.2-7.2)	1 (Reference)	0.85 (0.65-1.06)	0.85 (0.65-1.06)
236 (7.3-7.3)	1 (Reference)	0.84 (0.64-1.05)	0.84 (0.64-1.05)
237 (7.4-7.4)	1 (Reference)	0.83 (0.63-1.04)	0.83 (0.63-1.04)
238 (7.5-7.5)	1 (Reference)	0.82 (0.62-1.03)	0.82 (0.62-1.03)
239 (7.6-7.6)	1 (Reference)	0.81 (0.61-1.02)	0.81 (0.61-1.02)
240 (7.7-7.7)	1 (Reference)	0.80 (0.60-1.01)	0.80 (0.60-1.01)
241 (7.8-7.8)	1 (Reference)	0.79 (0.59-1.00)	0.79 (0.59-1.00)
242 (7.9-7.9)	1 (Reference)	0.78 (0.58-0.99)	0.78 (0.58-0.99)
243 (8.0-8.0)	1 (Reference)	0.77 (0.57-0.98)	0.77 (0.57-0.98)
244 (8.1-8.1)	1 (Reference)	0.76 (0.56-0.97)	0.76 (0.56-0.97)
245 (8.2-8.2)	1 (Reference)	0.75 (0.55-0.96)	0.75 (0.55-0.96)
246 (8.3-8.3)	1 (Reference)	0.74 (0.54-0.95)	0.74 (0.54-0.95)
247 (8.4-8.4)	1 (Reference)	0.73 (0.53-0.94)	0.73 (0.53-0.94)
248 (8.5-8.5)	1 (Reference)	0.72 (0.52-0.93)	0.72 (0.52-0.93)
249 (8.6-8.6)	1 (Reference)	0.71 (0.51-0.92)	0.71 (0.51-0.92)
250 (8.7-8.7)	1 (Reference)	0.70 (0.50-0.91)	0.70 (0.50-0.91)
251 (8.8-8.8)	1 (Reference)	0.69 (0.49-0.90)	0.69 (0.49-0.90)
252 (8.9-8.9)	1 (Reference)	0.68 (0.48-0.89)	0.68 (0.48-0.89)
253 (9.0-9.0)	1 (Reference)	0.67 (0.47-0.88)	0.67 (0.47-0.88)
254 (9.1-9.1)	1 (Reference)	0.66 (0.46-0.87)	0.66 (0.46-0.87)
255 (9.2-9.2)	1 (Reference)	0.65 (0.45-0.86)	0.65 (0.45-0.86)
256 (9.3-9.3)	1 (Reference)	0.64 (0.44-0.85)	0.64 (0.44-0.85)
257 (9.4-9.4)	1 (Reference)	0.63 (0.43-0.84)	0.63 (0.43-0.84)
258 (9.5-9.5)	1 (Reference)	0.62 (0.42-0.83)	0.62 (0.42-0.83)
259 (9.6-9.6)	1 (Reference)	0.61 (0.41-0.82)	0.61 (0.41-0.82)
260 (9.7-9.7)	1 (Reference)	0.60 (0.40-0.81)	0.60 (0.40-0.81)
261 (9.8-9.8)	1 (Reference)	0.59 (0.39-0.80)	0.59 (0.39-0.80)
262 (9.9-9.9)	1 (Reference)	0.58 (0.38-0.79)	0.58 (0.38-0.79)
263 (10.0-10.0)	1 (Reference)	0.57 (0.37-0.78)	0.57 (0.37-0.78)

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); HR, hazard ratio; 95% CI, 95% confidence interval.  
<sup>†</sup>By logistic regression model for DM. 95% CI shown.  
<sup>‡</sup>The HRs were adjusted for age, race/ethnicity, education, cigarette smoking, BMI, physical activity, alcohol intake, average triglyceride levels, history of DM, treatment therapy use, study site, and self-report of cardiovascular disease at baseline. Age was not included in models within age subgroups. Gender, race, and BMI were statistically associated in models that adjust for ethnicity and BMI subgroups.

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## Outcomes

A subset of women with and without a history of CVD were analyzed to address the effect of **confounding variables** and **selection bias**. There was still a statistically significant increase in incidence DM in the women on statin therapy, regardless of their CVD history (HR 1.46; 95% CI 1.29-1.65).

**Table 4. Risk of Diabetes Mellitus (DM) by Statin Use Among Women With and Without Medical History of Cardiovascular Disease (CVD) at Baseline**

Description	Women With CVD (n = 24 842)		Women Without CVD (n = 120 173)	
	Statin Users	Nonusers	Statin Users	Nonusers
Participants, No.	3338	21 504	7089	113 084
Incident DM cases, No.	369	1695	616	6796
Cumulative incidence rate, %	11.05	7.88	8.10	6.0
Unadjusted HR (95% CI) <sup>a</sup>	1.52 (1.36-1.71)	1 [Reference]	1.69 (1.52-1.70)	1 [Reference]
Age- and race/ethnicity-adjusted HR (95% CI) <sup>b</sup>	1.52 (1.36-1.70)	1 [Reference]	1.53 (1.49-1.75)	1 [Reference]
Multivariate adjusted HR (95% CI) <sup>c</sup>	1.46 (1.29-1.65)	1 [Reference]	1.48 (1.36-1.62)	1 [Reference]

Abbreviations: HR, hazard ratio; PH, proportional hazards.

<sup>a</sup>The HRs were estimated from Cox PH models.

<sup>b</sup>The HRs were estimated from Cox PH models, adjusted for age and race/ethnicity.

<sup>c</sup>The HRs were estimated from Cox PH models, adjusted for age, race/ethnicity, education, cigarette smoking, body mass index, physical activity, alcohol intake, energy intake, family history of DM, and hormone therapy use.

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## How Statins Could Impair Glucose and Insulin Metabolism

### Increased insulin resistance

- ↓ Adipocyte maturation (immature adipocytes are insulin resistant<sup>(a)</sup>)
- ↓ HMGCR in adipose → ↓ isoprenoids → ↓ GLUT4 → ↓ glucose uptake<sup>(b)</sup>
- ↓ Adipose SLC2A4 & C/EBPα → ↓ glucose uptake<sup>(a)</sup>
- ↓ Muscle Akt/FOXO signaling → ↓ glucose uptake<sup>(c)</sup>

### Decreased insulin secretion and β cell function

- ↓ GLUT2 in β cells → ↓ glucose uptake → ↓ insulin secretion<sup>(d)</sup>
- ↓ HMGCR in β cells → ↑ LDL uptake → paradoxical ↑ cholesterol → β cell damage<sup>(d)</sup>
- ↓ HMGCR in β cells → ↓ ubiquinone → ↓ mitochondrial function → ↓ ATP → ↓ insulin secretion<sup>(e)</sup>

a. Nakata M, et al. *Diabetologia*. 2006;49:1881-1892; b. Baker W, et al. *Diabetes Res Clin Pract*. 2010;87:98-107; c. Mallinson J, et al. *J Physiol*. 2009;587:219-230; d. Kruit J, et al. *Diabetologia*. 2010;53:1110-1119; e. Kruit J, et al. *Curr Opin Lipidol*. 2010;21:178-185.

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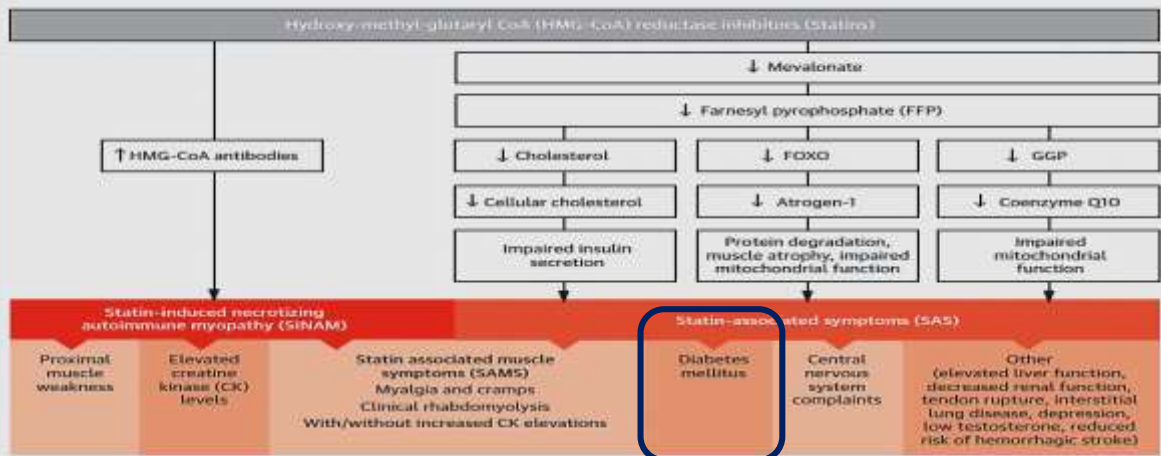
## Apoptosis of Beta Cells

- More cell death in beta cells in vitro exposed to various statins at different concentrations
- Reduced insulin secretion from beta cells exposed to statins impacts insulin response

Qian L, et al. *Med Sci Monit.* 2010;16:HY1-2.

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### CENTRAL ILLUSTRATION Statin-Associated Side Effects

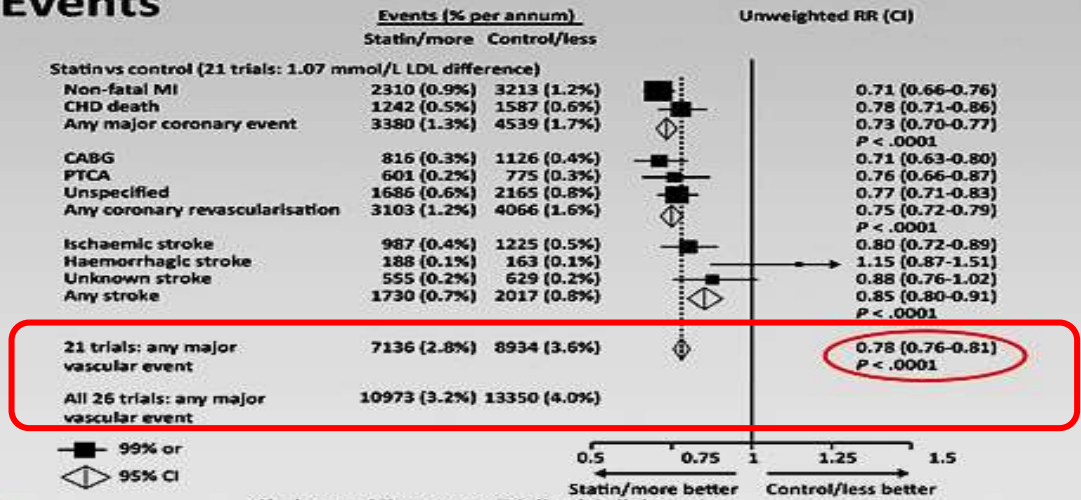


Thompson, P.D. et al. *J Am Coll Cardiol.* 2016;67(20):2395-410.

↓ = decreased function; ↑ = increased function; CK = creatine kinase; CNS = central nervous system symptoms; DM = diabetes mellitus; FFP = farnesyl pyrophosphate; FOXO = forkhead box protein group; GGP = geranylgeranyl pyrophosphate; HMG-CoA = hydroxyl-methyl-glutaryl-coenzyme A reductase; r = rhabdomyolysis; SAMS = statin-associated muscle symptoms; SAS = statin-associated symptoms; SINAM = statin-induced necrotizing autoimmune myopathy.

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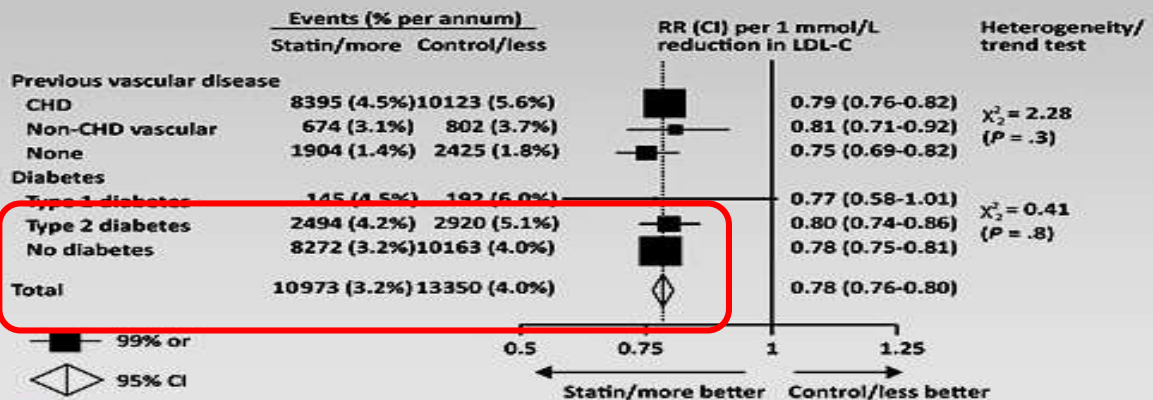
# Impact of Statin Use on Major Vascular Events



Cholesterol Treatment Trialists' Collaboration. *Lancet*. 2010;376:1670-1681.

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# Impact of Statin Use on Major Vascular Events by Baseline Prognostic Factors



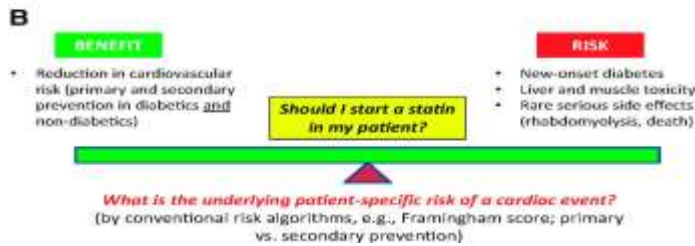
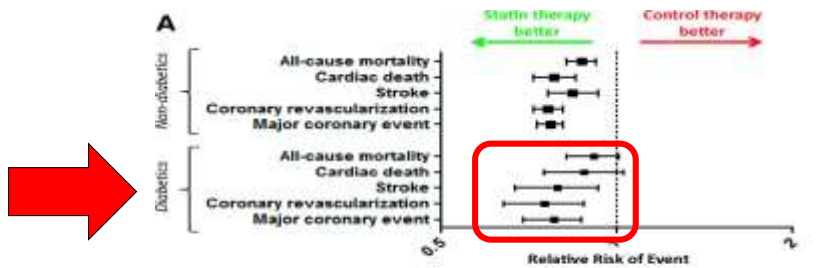
Cholesterol Treatment Trialists' Collaboration. *Lancet*. 2010;376:1670-1681.

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# To prescribe or not to prescribe: That is the statin question

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A, Relative risk of experiencing a cardiac event or death by diabetes status (for a near 40 mg/dL reduction in LDL cholesterol) from a meta-analysis of 14 clinical trials of statin therapy.



Ravi V. Shah, and Allison B. Goldfine *Circulation*. 2012;126:e282-e284



## TAKE AWAY MESSAGE

- YES STATINS INDUCE DIABETES IN PRE-DIABETICS
- THE TRUTH IS QUITE PROVED BY MANY META-ANALYSIS
- BUT

### Statin-Associated T2D Implications for Clinical Care

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- Do not discontinue statin
  - Exposes patients to CV risk
- Do not ignore elevated HbA<sub>1c</sub>
  - Manage T2D according to treatment guidelines
- Monitor HbA<sub>1c</sub>
- Counsel patients on lifestyle management
  - Diet, weight, exercise

### Statin Selection Consideration

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#### Identify patients at risk for new-onset T2D

- Patients with risk factors for T2D

#### In patients with high risk of developing T2D

- Consider a statin that has a low risk for new-onset T2D



**THANKS FOR YOUR KIND ATTENTION**

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